



Appendix A

Proposed Rules for the Medical Implant Communications Service

This appendix shows changes proposed for Part 95 of the Commission's Rules. Deletions appear as overstruck text. Additions appear as bold + double underlined text. In some cases, unchanged portions of Part 95 have been included in this appendix in order to provide a more complete sense of how the proposed regulations would interact with the current rules.

§ 2.106 Table of Frequency Allocations.

Show the Medical Implant Communications Service (MICS) as secondary in the Non-Government 402 - 403 and 403 - 405 MHz bands. Show FCC Rule Part 95 in column 6. Add a footnote NG as follows: "Medical Implant Communications Service (MICS) stations are authorized by rule without individual licenses on the conditions that harmful interference is not caused to stations in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and that MICS stations accept interference from stations in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services. Certain MICS stations are subject to the registration requirements set forth in Section 95.1115 of this Chapter."

§ 2.1204 Import conditions.

Add Subsection (9) to Section 2.1204(a) as follows:

(9) The radio frequency device is a medical implant transmitter implanted in a person granted entry into the United States or is a medical implant programmer/controller transmitter associated with such an implanted transmitter, provided, however that the transmitters covered by this provision otherwise comply with the technical requirements applicable to transmitters authorized to operate in the Medical Implant Communications Service under part 95 of this chapter. Such transmitters are permitted to be imported without the issuance of a grant of equipment authorization only for the personal use of the person in whom the medical implant transmitter has been implanted.

§ 95.401 (CB Rule 1) What are the Citizens Band Radio Services?

The Citizens Band Radio Services are:

(a) The Citizens Band (CB) Radio Service -- a private, two-way, short-distance voice communications service for personal or business activities of the general public. The CB Radio Service may also be used for voice paging.

(b) The Family Radio Service (FRS) -- a private, two-way, very short-distance voice communications service for facilitating family and group activities. The rules for this service are contained in Subpart B of this part.

(c) The Low Power Radio Service (LPRS) -- a private, short-distance communication service providing auditory assistance to persons with disabilities, persons who require language translation, and persons in educational settings, health care assistance to the ill, law enforcement tracking services in cooperation with law enforcement, and point-to-point network control communications for Automated Marine Telecommunications System (AMTS) coast stations licensed under part 80 of

this chapter. The rules for this service are listed under subpart G of this part. Two-way voice communications are prohibited.

(d) The Medical Implant Communications Service (MICS) -- a private ultra low power radio service for the transmission of non-voice data for the purpose of facilitating diagnostic and/or therapeutic functions involving implanted medical devices. The rules for this service are contained in Subpart H of this part.

§ 95.601 Basis and purpose.

This section provides the technical standards to which each transmitter (apparatus that converts electrical energy received from a source into RF (radio frequency) energy capable of being radiated) used or intended to be used in a station authorized in any of the Personal Radio Services must comply. This section also provides requirements for obtaining type acceptance or type certification for such transmitters. The Personal Radio Services are the GMRS (General Mobile Radio Service)--subpart A, the Family Radio Service (FRS)--subpart B, the R/C (Radio Control Radio Service)--subpart C, the CB (Citizens Band Radio Service)--subpart D, and the Low Power Radio Service (LPRS)--subpart G, **and the Medical Implant Communications Service (MICS)--subpart H.**

§ 95.603 Type acceptance or certification required.

(a) Each GMRS transmitter (a transmitter that operates or is intended to operate at a station authorized in the GMRS) must be type accepted.

(b) Each R/C transmitter (a transmitter that operates or is intended to operate at a station authorized in the R/C) must be type accepted, except one that transmits only in the 26-27 MHz frequency band and is crystal controlled (where the transmitted frequency is established by a crystal (a quartz piezo-electric element)).

(c) Each CB transmitter (a transmitter that operates or is intended to operate at a station authorized in the CB) must be type accepted. No CB transmitter type accepted pursuant to an application filed prior to September 10, 1976, shall be manufactured or marketed.

(d) Each FRS unit (a transmitter that operates or is intended to operate in the FRS) must be certified for use in the FRS in accordance with Subpart J of Part 2 of this chapter.

(e) Each Low Power Radio Service transmitter (a transmitter that operates or is intended to operate in the LPRS) must be type accepted.

(f) Each Medical Implant Communications Service transmitter (a transmitter that operates or is intended to operate in the MICS) must be type accepted, except for medical implant

transmitters that are not marketed for use in the United States, but which otherwise comply with the MICS technical requirements and are operated in the United States by individuals who have traveled to the United States from abroad.

§ 95.605 Type acceptance and certification procedures.

Any entity may request type acceptance for its transmitter when the transmitter is used in the GMRS, R/C, CB, IVDS, ~~or~~ LPRS or MICS following the procedures in part 2 of this chapter. Medical implant transmitters shall be tested for emissions and EIRP limit compliance while enclosed in a medium that simulates the tissue in which the transmitter is to be implanted. Frequency stability testing for MICS transmitters shall be performed over the temperature range set forth in § 95.630.

Any entity may request certification for its transmitter when the transmitter is used in the FRS following the procedures in part 2 of this chapter.

* * *

§ 95.630 MICS Transmitter frequencies and stability.

(a) Stations may operate on any of the frequencies in the band 402.000 - 405.000 MHz, provided that the out-of-band emissions are attenuated in accordance with the requirements of § 95.635.

(b) The authorized bandwidth of the emission from a MICS station shall not exceed 300 kHz.

(c) The frequency stability of MICS transmitters shall be sufficient to maintain compliance with the emission limits of § 95.635 over the range:

(1) 12°C to 55°C in the case of medical implant transmitters; and

(2) 0°C to 70°C in the case of medical implant programmer/control transmitters.

§ 95.631 Emission types.

(a) A GMRS transmitter must transmit only emission types A1D, F1D, G1D, H1D, J1D, R1D, A3E, F3E, G3E, H3E, J3E or R3E. A non-voice emission is limited to selective calling or tone-operated squelch tones to establish or continue voice communications. See § 95.181 (g) and (h).

(b) An R/C transmitter may transmit any appropriate non-voice emission which meets the emission limitations of § 95.633.

(c) A CB transmitter may transmit only emission types A1D, H1D, J1D, R1D, A3E, H3E, J3E, R3E. A non-voice emission is limited to selective calling or tone-operated squelch tones to establish or continue voice communications. See § 95.412 (b) and (c).

(d) An FRS unit may transmit only emission type F3E. A non-voice emission is limited to selective calling or tone-operated squelch tones to establish or continue voice communications.

(e) No GMRS or CB transmitter shall employ a digital modulation or emission.

(f) No GMRS, CB or R/C transmitter shall transmit non-voice data.

(g) An LPRS station may transmit any emission type appropriate for communications in this service. Two-way voice communications, however, are prohibited.

(h) A MICS station may transmit any emission type appropriate for communications in this service. Voice communications, however, are prohibited.

§ 95.633 Emission bandwidth.

(a) The authorized bandwidth (maximum permissible bandwidth of a transmission) for emission type H1D, J1D, R1D, H3E, J3E or R3E is 4 kHz. The authorized bandwidth for emission type A1D or A3E is 8 kHz. The authorized bandwidth for emission type F1D, G1D, F3E or G3E is 20 kHz.

(b) The authorized bandwidth for any emission type transmitted by an R/C transmitter is 8 kHz.

(c) The authorized bandwidth for emission type F3E transmitted by a FRS unit is 12.5 kHz.

(d) For transmitters in the LPRS:

(1) The authorized bandwidth for narrowband frequencies is 4 kHz and the channel bandwidth is 5 kHz

(2) The channel bandwidth for standard band frequencies is 25 kHz.

(3) The channel bandwidth for extra band frequencies is 50 kHz.

(4) AMTS stations may use the 216.750-217.000 MHz band as a single 250 kHz channel so long as the signal is attenuated as specified in § 95.635(c).

(e) For transmitters in the MICS:

(1) The maximum authorized bandwidth is 300 kHz.

(2) Lesser authorized bandwidths may be employed, provided that the unwanted emissions are attenuated as provided in § 95.635 and that the average power radiated in any 300 kHz bandwidth does not exceed 25 microwatts EIRP. See Section 95.605 concerning measurement procedures.

§ 95.635 Unwanted radiation.

(a) In addition to the procedures in Part 2, the following requirements apply to each transmitter both with and without the connection of all attachments acceptable for use with the transmitter, such as an external speaker, microphone, power cord, antenna, etc.

(b) The power of each unwanted emission shall be less than TP as specified in the applicable paragraph:

Transmitter	Emission type	Applicable paragraphs
GMRS	A1D, A3E, F1D, G1D, F3E, G3E with filtering	(1)(3)(7)
	A1D, A3E, F1D, G1D, F3E, G3E without filtering	(5)(6)(7)
	H1D, J1D, R1D, H3E, J3E, R3E	(2)(4)(7)
FRS	F3E with filtering	(1)(3)(7)
NOTE: Filtering refers to the requirement in § 95.635(b).		
R/C		
27 MHz band	As specified in § 95.629(b)	(1)(3)(7)
72-76 MHz band	As specified in § 95.629(b)	(1)(3)(7)(10)(11)(12)
CB	A1D, A3E	(1)(3)(8)(9)
	H1D, J1D, R1D, H3E, J3E, R3E	(2)(4)(8)(9)
	A1D, A3E type accepted before September 10, 1976	(1)(3)(7)

(c) For transmitters designed to operate in the LPRS, emissions shall be attenuated in accordance with the following:

(1) Emissions for LPRS transmitters operating on standard band channels (25 kHz) shall be attenuated below the unmodulated carrier in accordance with the following:

(i) Emissions 12.5 kHz to 22.5 kHz away from the channel center frequency: at least 30 dB; and

(ii) Emissions more than 22.5 kHz away from the channel center frequency: at least $43 + 10 \log(\text{carrier power in watts})$ dB.

(2) Emissions for LPRS transmitters operating on extra band channels (50 kHz) shall be attenuated below the unmodulated carrier in accordance with the following:

(i) Emissions 25 kHz to 35 kHz from the channel center frequency: at least 30 dB; and

(ii) Emissions more than 35 kHz away from the channel center frequency: at least $43 + 10 \log(\text{carrier power in watts})$ dB.

(3) Emissions for LPRS transmitters operating on narrowband channels (5 kHz) shall be attenuated below the power (P) of the highest emission, measured in peak values, contained within the authorized bandwidth (4 kHz) in accordance with the following:

(i) On any frequency within the authorized bandwidth: Zero dB;

(ii) On any frequency removed from the center of the authorized bandwidth by a displacement frequency (f_d in kHz) of more than 2 kHz up to and including 3.75 kHz: The lesser of $30 + 20(f_d - 2)$ dB, or $55 + 10 \log(P)$, or 65 dB; and

(iii) On any frequency beyond 3.75 kHz removed from the center of the authorized bandwidth: At least $55 + 10 \log(P)$ dB.

(4) Emissions from AMTS transmitters using a single 250 kHz channel shall be attenuated below the unmodulated carrier in accordance with the following:

(i) Emissions from 125 kHz to 135 kHz away from the channel center frequency; at least 30 dB; and

(ii) Emissions more than 135 kHz away from the channel center frequency; at least 43 + 10 log(carrier power in watts) dB.

(d) For transmitters designed to operate in the MICS, emissions shall be attenuated in accordance with the following:

(1) Emissions more than 250 kHz outside of the MICS band (402.000 - 405.000 MHz) shall be attenuated to a level no greater than the following field strength limits:

<u>Frequency</u> <u>(MHz)</u>	<u>Field Strength</u> <u>(microvolts/meter)</u>	<u>Measurement Distance</u> <u>(meters)</u>
30 - 88	100	3
88 - 216	150	3
216 - 960	200	3
Above 960	500	3

In the emission table above, the tighter limit applies at the band edges.

(2) The emission limits shown in the above table are based on measurements employing a CISPR quasi-peak detector except above 1000 MHz, in which case the limit is based on measurements employing an average detector. See Section 95.605 concerning measurement procedures.

(3) The emissions from a MICS transmitter must be measured to beyond the tenth harmonic of the highest fundamental frequency designed to be emitted by the transmitter.

(4) Emissions more than 150 kHz away from the center frequency shall be attenuated below the transmitter output power at least 20 dB, except as provided in §95.635(d)(1).

§ 95.637 Modulation standards. [No change]

(a) A GMRS transmitter that transmits emission types F1D, G1D, or G3E must not exceed a peak frequency deviation of plus or minus 5 kHz. A GMRS transmitter that transmits emission type F3E must not exceed a peak frequency deviation of plus or minus 5 kHz. A FRS unit that transmits emission type F3E must not exceed a peak frequency deviation of plus or minus 2.5 kHz, and the audio frequency response must not exceed 3.125 kHz.

(b) Each GMRS transmitter, except a mobile station transmitter with a power output of 2.5 W or less, must automatically prevent a greater than normal audio level from causing overmodulation.

The transmitter also must include audio frequency low pass filtering, unless it complies with the applicable paragraphs of § 95.631 (without filtering.) The filter must be between the modulation limiter and the modulated stage of the transmitter. At any frequency (f in kHz) between 3 and 20 kHz, the filter must have an attenuation of at least $60 \log_{10} (f/3)$ dB greater than the attenuation at 1 kHz. Above 20 kHz, it must have an attenuation of at least 50 dB greater than the attenuation at 1 kHz.

(c) When emission type A3E is transmitted, the modulation must be greater than 85% but must not exceed 100%. Simultaneous amplitude modulation and frequency or phase modulation of a transmitter are not permitted.

(d) When emission type A3E is transmitted by a CB transmitter having a TP of greater than 2.5 W, the CB transmitter must automatically prevent the modulation from exceeding 100%.

(e) Each CB transmitter that transmits emission type H3E, J3E or R3E must be capable of transmitting the upper sideband. The capability of also transmitting the lower sideband is permitted.

§ 95.639 Maximum transmitter power.

(a) No GMRS transmitter, under any condition of modulation, shall exceed:

(1) 50 W Carrier power (average TP during one unmodulated RF cycle) when transmitting emission type A1D, F1D, G1D, A3E, F3E or G3E.

(2) 50 W peak envelope TP when transmitting emission type H1D, J1D, R1D, H3E, J3E or R3E.

(b) No R/C transmitter, under any condition of modulation, shall exceed a carrier power or peak envelope TP (single-sideband only) of:

(1) 4 W in the 26-27 MHz frequency band, except on channel frequency 27.255 MHz;

(2) 25 W on channel frequency 27.255 MHz;

(3) 0.75 W in the 72-76 MHz frequency band.

(c) No CB transmitter, under any condition of modulation, shall exceed:

(1) 4 W Carrier power when transmitting emission type A1D or A3E;

(2) 12 W peak envelope TP when transmitting emission type H1D, J1D, R1D, H3E, J3E or R3E. Each CB transmitter which transmits emission type H3E, J3E or R3E must automatically prevent the TP from exceeding 12 W peak envelope TP or the manufacturer's rated peak envelope TP, whichever is less.

(d) No FRS unit, under any condition of modulation, shall exceed 0.500 W effective radiated power (ERP).

(e) The maximum transmitter output power authorized for LPRS stations is 100 mW.

(f) In the MICS the following limits apply:

(1) The maximum EIRP for programmer/control stations in the MICS is 25 microwatts, provided, however, that the antenna associated with the transmitter must be supplied with the transmitter and shall be considered part of the transmitter subject to the equipment authorization for the transmitter. The antenna and the transmitter shall be designed to ensure that no antenna other than that furnished by the holder of the equipment authorization for the transmitter shall be used with the transmitter. The use of a permanently attached antenna or an antenna that uses a unique coupling to the transmitter shall be considered sufficient to comply with these provisions, provided that any transmission line to be used between the transmitter and antenna shall be of a length and type approved with the transmitter and supplied with the transmitter by the holder of the equipment authorization. The transmitter may be designed so that a broken antenna can be replaced by the user with an antenna approved by the holder of the grant of equipment authorization, but the use of a standard antenna jack or electrical connector is prohibited.

(2) The maximum field strength from an implanted implant transmitter is 9.1 mV/m (rms) at 3 meters as measured with an instrument having a peak detector function. See Section 95.605 concerning measurement procedures. The antenna for a medical implant transmitter must be supplied with the transmitter and shall be considered part of the transmitter subject to the equipment authorization for the transmitter. The antenna and the transmitter shall be designed to ensure that no antenna other than that furnished by the holder of the equipment authorization for the transmitter shall be used with the transmitter. The use of a permanently attached antenna or an antenna that uses a unique coupling to the transmitter shall be considered sufficient to comply with these provisions.

(3) The average power radiated in any 300 kHz bandwidth shall not exceed 25 microwatts EIRP. See Section 95.633(e)(4).

§ 95.645 Control accessibility. [No change]

(a) No control, switch or other type of adjustment which, when manipulated, can result in a violation of the rules shall be accessible from the transmitter operating panel or from exterior of the transmitter enclosure.

(b) An R/C transmitter which incorporates plug-in frequency determining modules which are changed by the user must be type accepted with the modules. Each module must contain all of the

frequency determining circuitry including the oscillator. Plug-in crystals are not considered modules and must not be accessible to the user.

§ 95.647 FRS unit and R/C transmitter antennas. [No change]

The antenna of each FRS unit, and the antenna of each R/C station transmitting in the 72-76 MHz band, must be an integral part of the transmitter. The antenna must have no gain (as compared to a half-wave dipole) and must be vertically polarized.

§ 95.649 Power capability.

No CB, R/C, LPRS, MICS transmitter, or FRS unit shall incorporate provisions for increasing its transmitter power to any level in excess of the limits specified in § 95.639.

§ 95.651 Crystal control required.

All transmitters used in the Personal Radio Services must be crystal controlled, except an R/C station that transmits in the 26-27 MHz frequency band, a FRS unit, ~~and~~ a LPRS unit, or a MICS transmitter.

§ 95.653 Instructions and warnings. [No change]

(a) A user's instruction manual must be supplied with each transmitter marketed, and one copy (a draft or preliminary copy is acceptable provided a final copy is provided when completed) must be forwarded to the FCC with each request for type acceptance.

(b) The instruction manual must contain all information necessary for the proper installation and operation of the transmitter including:

(1) Instructions concerning all controls, adjustments and switches that may be operated or adjusted without resulting in a violation of the rules.

(2) Warnings concerning any adjustment that could result in a violation of the rules or that is recommended to be performed by or under the immediate supervision and responsibility of a person certified as technically qualified to perform transmitter maintenance and repair duties in the private land mobile services and fixed services by an organization or committee representative of users of those services.

(3) Warnings concerning the replacement of any transmitter component (crystal, semiconductor, etc.) that could result in a violation of the rules.

(4) For a GMRS transmitter, warnings concerning licensing requirements and information concerning license application procedures.

§ 95.655 Frequency capability. [No change]

(a) No transmitter will be type accepted for use in the CB service if it is equipped with a frequency capability not listed in § 95.625, and no transmitter will be type accepted for use in the GMRS if it is equipped with a frequency capability not listed in § 95.621, unless such transmitter is also type accepted for use in another radio service for which the frequency is authorized and for which type acceptance is also required. (Transmitters with frequency capability for the Amateur Radio Services, Military Affiliate Radio System and Civil Air Patrol will not be type accepted.)

(b) All frequency determining circuitry (including crystals) and programming controls in each CB transmitter and in each GMRS transmitter must be internal to the transmitter and must not be accessible from the exterior of the transmitter operating panel or from the exterior of the transmitter enclosure.

(c) No add-on device, whether internal or external, the function of which is to extend the transmitting frequency capability of a CB transmitter beyond its original capability, shall be manufactured, sold or attached to any CB station transmitter.

Appendix 1 to Subpart E -- Glossary of Terms

The definitions used in part 95, subpart E are:

Authorized bandwidth. Maximum permissible bandwidth of a transmission.

Carrier power. Average TP during one unmodulated RF cycle.

CB. Citizens Band Radio Service.

CB transmitter. A transmitter that operates or is intended to operate at a station authorized in the CB.

Channel frequencies. Reference frequencies from which the carrier frequency, suppressed or otherwise, may not deviate by more than the specified frequency tolerance.

Crystal. Quartz piezo-electric element.

Crystal controlled. Use of a crystal to establish the transmitted frequency.

dB. Decibels.

EIRP. Effective Isotropic Radiated Power. Antenna input power times gain, expressed in watts, where the gain is referenced to an isotropic radiator.

FCC. Federal Communications Commission.

FRS. Family Radio Service.

Filtering. Refers to the requirement in s 95.633(b).

GMRS. General Mobile Radio Service.

GMRS transmitter. A transmitter that operates or is intended to operate at a station authorized in the GMRS.

Harmful interference. Any transmission, radiation or induction that endangers the functioning of a radionavigation or other safety service or seriously degrades, obstructs or repeatedly interrupts a radiocommunication service operating in accordance with applicable laws, treaties and regulations.

Mean power. TP averaged over at least 30 cycles of the lowest modulating frequency, typically 0.1 seconds at maximum power.

MICS. Medical Implant Communications Service.

Medical implant device. Apparatus that is placed inside the human body for the purpose of performing diagnostic or therapeutic functions.

Medical implant event. An occurrence or the lack of an occurrence recognized by a medical implant device that requires the transmission of data from a medical implant transmitter in order to protect the safety or well-being of the person in whom the medical implant transmitter has been implanted.

Medical Implant Communications Service (MICS) transmitter. A transmitter authorized to operated in the MICS.

Medical implant programmer/control transmitter. A MICS transmitter that operates or is designed to operate outside of a human body for the purpose of communicating with a receiver connected to a medical implant device.

Medical implant transmitter. A MICS transmitter that operates or is designed to operate within a human body for the purpose of facilitating communications from a Medical Implant Device.

Peak envelope power. TP averaged during 1 RF cycle at the highest crest of the modulation envelope.

R/C. Radio Control Radio Service.

R/C transmitter. A transmitter that operates or is intended to operate at a station authorized in the R/C.

RF. Radio frequency.

Transmitter. Apparatus that converts electrical energy received from a source into RF energy capable of being radiated.

TP. RF transmitter power expressed in W, either mean or peak envelope, as measured at the transmitter output antenna terminals.

W. Watts.

A new Subpart H is created.

Subpart H - Medical Implant Communications Service (MICS)

§ 95.1101 Eligibility

Operation in the MICS is permitted by rule without an individual license issued by the FCC. A person is permitted to operate medical implant transmitters connected to medical implant devices that have been implanted in that person by a duly authorized health care professional and medical implant programmer/control transmitters associated with their medical implant transmitter(s). Duly authorized health care professionals are permitted by rule to operate MICS transmitters. Manufacturers of medical implant devices and MICS transmitters and their representatives are authorized to operate transmitters in this service for the purpose of demonstrating such equipment to duly authorized health care professionals. No entity that is a foreign government or which is acting in its capacity as a representative of a foreign government is eligible to operate a MICS transmitter. The term "duly authorized health care professional" means a physician or other individual authorized under state or federal law to provide health care services using medical implant devices. Operations that comply the requirements of this Part may be conducted under manual or automatic control.

§ 95.1103 Authorized locations.

MICS operation is authorized anywhere CB station operation is authorized under § 95.405.

§ 95.1105 Station Identification.

A MICS station is not required to transmit a station identification announcement.

§ 95.1007 Station inspection.

All non-implanted MICS apparatus must be made available for inspection upon request by an authorized FCC representative. Persons operating implanted medical implant transmitters shall cooperate reasonably with duly authorized FCC representatives in the resolution of interference.

§ 95.1109 Permissible communications.

MICS stations may transmit non-voice data as permitted below:

(a) Except for the purposes of testing and for demonstrations to health care professionals medical implant programmer/control transmitters may transmit only operational, diagnostic and therapeutic information associated with a medical implant device that has been implanted by a duly authorized health care professional. Except in response to a medical implant event, no medical implant transmitter shall transmit except in response to a transmission from a medical implant programmer/control transmitter or a non-radio frequency actuation signal generated by a device external to the body in which the medical implant transmitter is implanted or is to be implanted.

(b) Except for the purposes of testing and for demonstrations to health care professionals medical implant programmer/control transmitters may transmit only operational, diagnostic and therapeutic information associated with a medical implant device.

§ 95.1111 Channel use policy.

(a) The channels authorized for MICS operation by this part of the FCC Rules are available on a shared basis only and will not be assigned for the exclusive use of any entity.

(b) Those using MICS transmitters must cooperate in the selection and use of channels in order to reduce interference and make the most effective use of the authorized facilities. Channels must be selected in an effort to avoid interference to other MICS transmissions.

(c) Operation is subject to the condition that no harmful interference is caused to stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids, Meteorological Satellite, or Earth Exploration Satellite Services. MICS stations must accept any interference from stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids, Meteorological Satellite, or Earth Exploration Satellite Services.

§ 95.1113 Antennas.

No antenna for a MICS programmer/control transmitter shall be configured for permanent outdoor use, provided, however, that any antenna used outdoors shall not be affixed to any structure for which the height to the tip of the antenna will exceed three (3) meters (9.8 feet) above ground.

§ 95.1115 Disclosure policies and Registration.

(a) Manufacturers of MICS transmitters must include with each transmitting device the following statement: "This transmitter is authorized by rule under the Medical Implant Communications Service (47 C.F.R. Part 95) and must not cause harmful interference to stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids (i.e. transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such aids, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Implant Communications Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that any particular transmission from this transmitter will be free from interference."

(b) The holder of the grant of equipment authorization shall include with each MICS programmer/control transmitter a notice that the entity responsible for the operation of the MICS programmer/control transmitter shall, before using the device, register with the holder of the grant of equipment authorization. In the event that control of the device is transferred, it shall be reregistered in the name of the new entity having responsibility for its operation. The notice may be included with the instruction manual for the device or as a separate enclosure with the device. Such registration shall include the name and mailing address of the

entity, the serial number of the programmer/control transmitter, and a telephone number for the entity that can be use to notify the entity if interference from the programmer/control transmitter is suspected. Such registration information shall be maintained by the holder of the grant of equipment authorization for a period of at least ten years and made available, upon request, to the FCC in the event that interference from the device is suspected.

§ 95.1117 Labeling requirements.

(a) Medical implant programmer/controller transmitters shall be labeled as provided in part 2 of this chapter and shall bear the following statement in a conspicuous location on the device:

This device may not interfere with stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation. Prior to initial operation, the entity that will be responsible for the operation of this device must register its name, mailing address, telephone number, and the serial number of this device with [name and address of equipment authorization grantee] as required by the FCC rules.

Note: In lieu of an address for the equipment authorization grantee, a telephone number may be provided. Where such devices are leased, the lessor may provide to the equipment authorization grantee the information required by this section with respect to each lessee.

(b) Where a medical implant programmer/controller transmitter is constructed in two or more sections connected by wire and marketed together, the statement specified in this section is required to be affixed only to the main control unit.

(c) Medical implant transmitters shall be identified with a serial number. The FCC ID number associated with the transmitter and the information required by Section 2.925 of the FCC Rules may be placed in the instruction manual for the transmitter and on the shipping container for the transmitter, in lieu of being placed directly on the transmitter.

§ 95.1119 Marketing limitations.

Transmitters intended for operation in the MICS may be marketed and sold only for those uses described in § 95.1109 of this chapter.

Note: Section 95.1019 is amended to change the reference in it from "95.1109" to "95.1009."

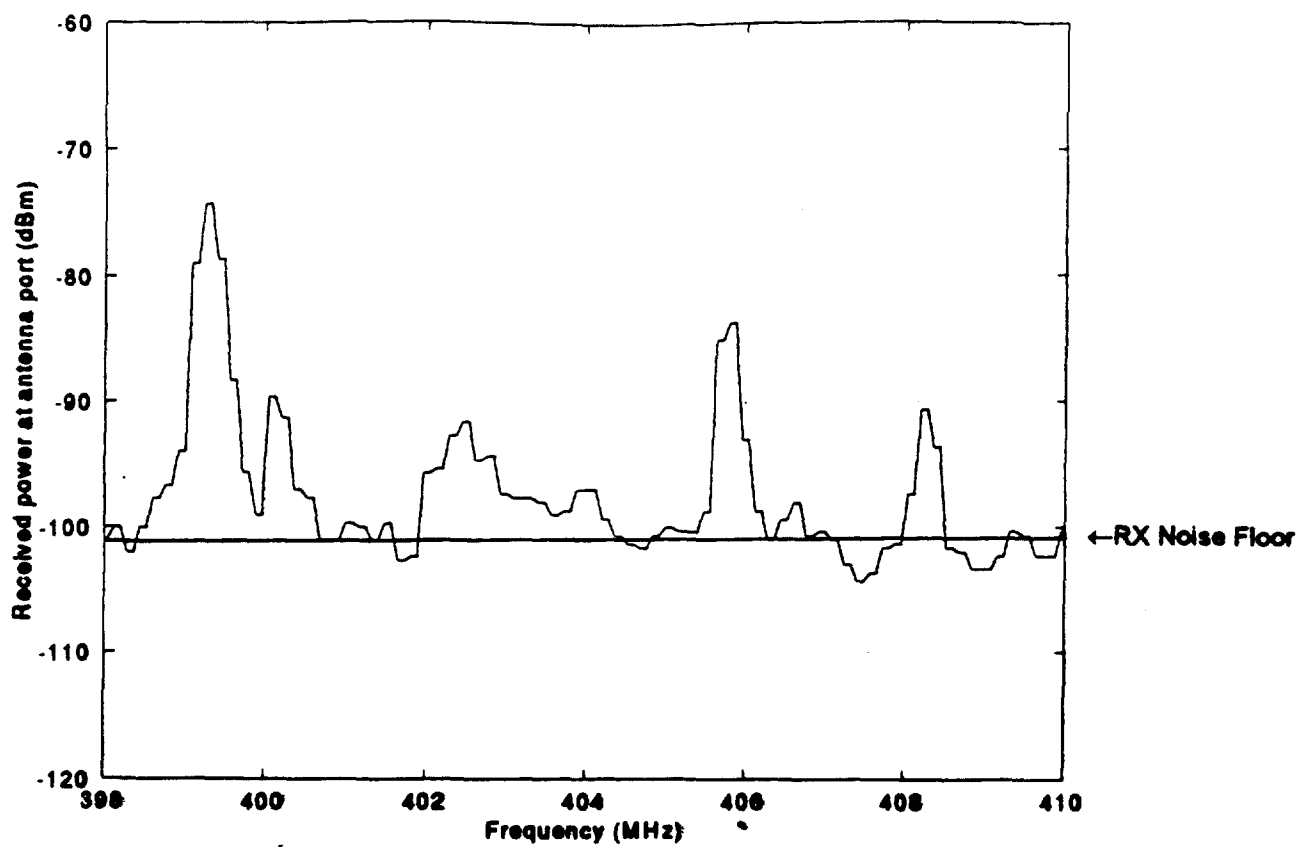


ALL-STATE LEGAL 800-222-0510 E0511 RECYCLED

Appendix B

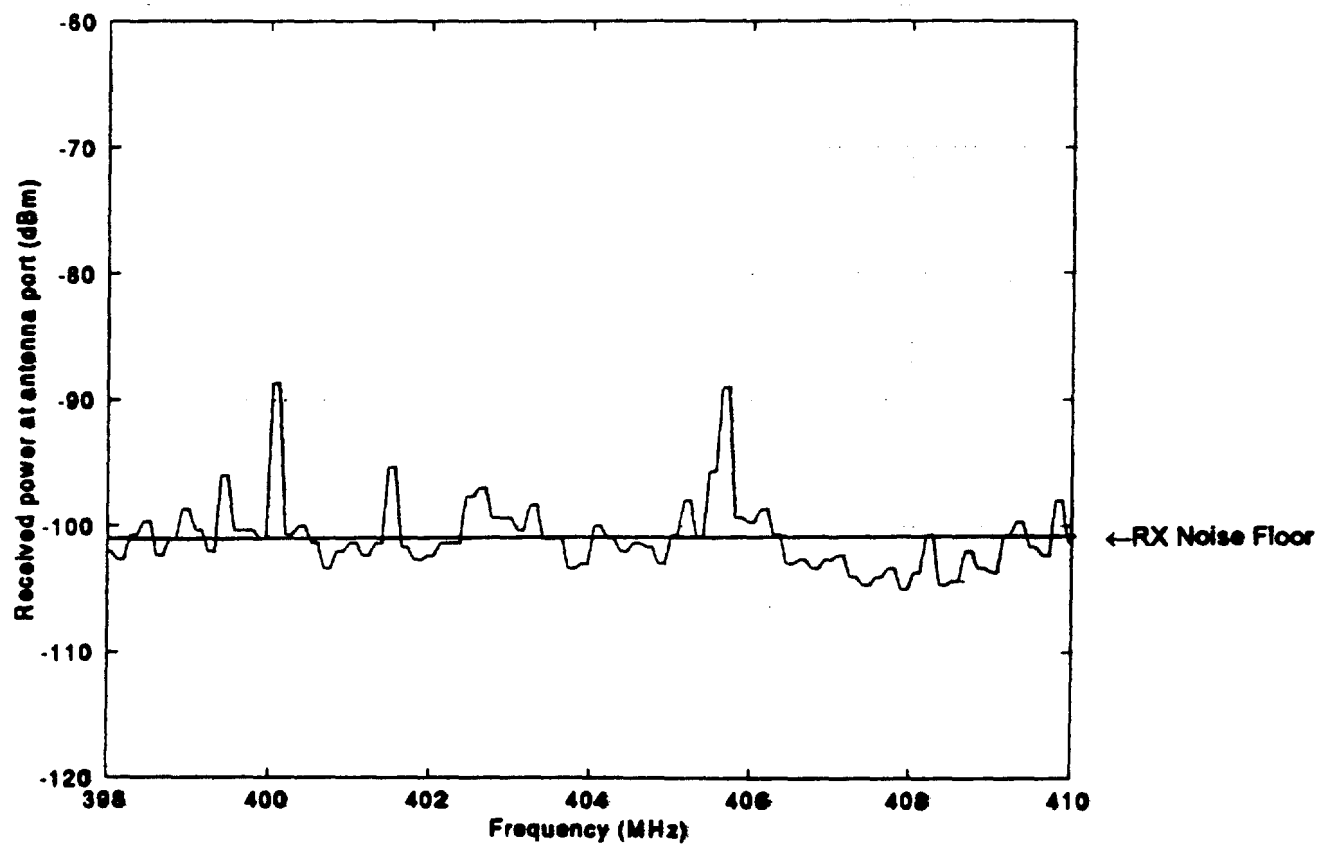
Representative Noise Measurements

Medtronic has commissioned noise measurements in thirteen sites around the world where MICS equipment is likely to be used. The representative data depicted on the following spectrum graphs support the conclusion that MICS systems should be frequency agile and have three MHz of spectrum within which to seek a usable (*i.e.* relatively low noise) channel.



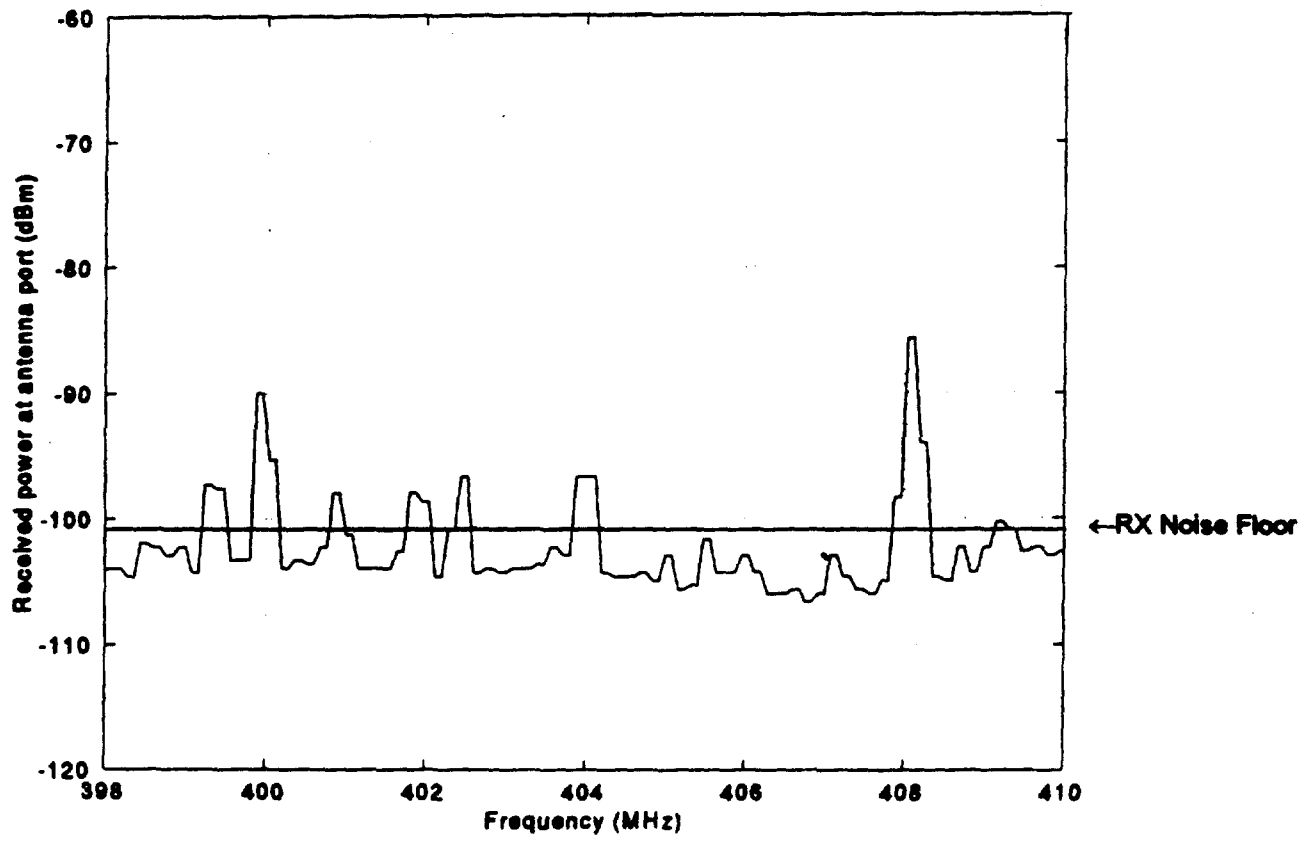
Herz- und Diabeteszentrum Nordrhein-Westfalen
in Bad Oeynhausen, Germany
(small town 2 hours drive from Düsseldorf)

Fig. 1



Harefield Heart Hospital
Harefield, England

Fig. 2



University of Leuven Hospital
Leuven, Belgium

Fig. 3



Appendix C

Compatibility Analysis for the Sharing of Spectrum Between Medical Implant Communications Systems and the Meteorological Aids Service